



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JAN 8 2009

Re: Lucentis

Docket Nos.: FDA-2007-E-0461

FDA-2007-E-0165

FDA-2007-E-0459

The Honorable Jon Dudas

Under Secretary of Commerce for Intellectual Property

Director of the United States Patent and Trademark Office

Mail Stop Hatch-Waxman PTE

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 6,407,213; 6,884,879; and 7,060,269 filed by Genentech, Inc., under 35 U.S.C. § 156. The patent claims Lucentis (ranibizumab), biologic license application (BLA) 125156/0.

In the May 29, 2008, issue of the Federal Register (73 Fed. Reg. 30949), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 25, 2008, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Jeffrey P. Kushan  
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